DEC 1 8 2000

SECTION 5. 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax Number of the Applicant

Thoratec Laboratories Corporation
Pleasanton, California 94588
(925) 847-8600
(925) 847-8628 fax

B. Contact Person

Donald A. Middlebrook
Vice President, Regulatory Affairs and Quality Assurance
6035 Stoneridge Drive
Pleasanton, California 94588
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C. Date Prepared

June 23, 2000

D. Device Name

Proprietary Name:	Thoratec® *Vectra*™ Vascular Access Graft
Trade name:	Vascular Access Graft
Classification name:	Vascular Graft
Predicate device:	Impra, W.L. Gore ePTFE vascular grafts

E. Device Description

Thoratec® *Vectra*™ Vascular Access Graft (*Vectra*™) is a compliant, elastomeric, non-tapered tube constructed of a proprietary polymer called Thoralon™ with graduated reinforcement along the entire length of the graft. The densely reinforced section in the middle is identified by the orientation line. The grafts are manufactured in two sizes of 5mm and 6mm internal diameter, each with a wall approximately 1.0 mm thick and a maximum usable length of 50 cm. Devices specifically intended for post implant revisions are also available.

F. Device Intended Use

The Thoratec® *Vectra*™ Vascular Access Graft is indicated for use as a subcutaneous arteriovenous conduit for blood access.

G. Substantial Equivalence Summary

The *Vectra*™ Vascular Access Graft is substantially equivalent in design and intended use to the commercially available IMPRA ePTFE Vascular Graft (K791810, K801621) and the W.L. Gore & Associates, Inc. ePTFE Vascular Graft (Pre-amendment). Other than the difference in the material of construction, the *Vectra*™ Vascular Access Graft and predicate devices have the same intended use and the method of use.

H. Device Testing

Bench, animal and clinical studies were performed in accordance with the Food and Drug Administration draft guidance document *"Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses,"* (Food and Drug Administration, August 1993), and the Association for the Advancement of Medical Devices (AAMI) standard entitled *"Cardiovascular Implants - Vascular Prostheses"* (AAMI VP20-1994). A prospective randomized clinical study compared the Thoratec *Vectra*™ graft to ePTFE to establish equivalency in the safety and effectiveness for the *Vectra*™ and ePTFE grafts when used as subcutaneous

arteriovenous conduits. In the clinical study, 142 patients were randomized equally to both grafts (*Vectra*™ = 71, ePTFE = 71) at 5 institutions in the US.

In conclusion, non-clinical and clinical testing supports the finding that *Vectra*™ Vascular Access Grafts are substantially equivalent to predicate ePTFE grafts when used as subcutaneous arteriovenous conduits in accordance with the Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2000

THORATEC LABORATORIES
c/o Rajagopal Kowligi, Ph.D.
Manager, Regulatory Affairs
6035 Stoneridge Drive
Pleasanton, CA 94588

Re: K001927
Trade Name: Thoratec *Vectra*™ Vascular Access Graft-5MM Diameter, 6MM
Regulatory Class: DSY (CLASS II (two)) & DYF (CLASS III (three))
Product Code: DSY (CLASS II (two)) & DYF (CLASS III (three))
Dated: November 14, 2000
Received: November 15, 2000

Dear Dr. Kowligi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K001927

Device Name: Thoratec® *Vectra*™ Vascular Access Graft

Indications For Use: The *Vectra*™ Vascular Access Graft is indicated for use as a subcutaneous arteriovenous conduit for blood access.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001927

(Optional Format 1-2-96)